

K050266 DIRECT BILIRUBIN LIQUICOLOR AND TOTAL BILIRUBIN LIQUICOLORJun 30, 2005
146 days to decisionK050266 · Product code: JFM · Chemistry
Source: <https://www.510kdatabase.net/k050266/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Bilirubin (JFM)
Date received	Feb 4, 2005
Decision date	Jun 30, 2005
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stanbio Laboratory
Location	Mchenry, IL, US
Contact	KIRK JOHNSON
510(k) history	47 submissions · 47 cleared · 1977-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050266/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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